

(April-February) were lower by 11.8 per cent and 1.6 per cent over corresponding previous period. The recent fall in gold price may also lead to a fall in the value of gold imports for investment purposes.

Clinical trials on children at Safdarjung hospital, Delhi

3784. DR. JANARDHAN WAGHMARE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware of clinical trials on children particularly on new borns by foreign pharmaceutical firms at Government's Safdarjung Hospital;

(b) if so, the exact number of children died in Safdarjung Hospital during the past few years;

(c) whether Government proposes to conduct a judicial inquiry into the untimely deaths of a large number of children in the hospital during the last three years;

(d) if so, by when and, if not, the reasons therefor; and

(e) the other steps Government proposes to take to ensure that foreign pharmaceutical firms are not allowed to conduct clinical trials on humans across the country?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) There is no report regarding the conduct of clinical trials on children particularly on new borns by foreign pharmaceutical firms at Safdarjung Hospital, New Delhi.

(e) Research in the area of drug discovery leads to newer, safer and more efficacious drugs being made available in the country. Clinical trials are the only way of establishing the safety and efficacy of any new drug before its introduction in the market for human use. Clinical trials (with safeguards) are necessary for introduction of new drugs for a country like India, considering its disease burden and emergence of new variants of disease. The trials in the long run benefit the country and its patients. However, lesser number of clinical trials are taking place in the country as compared to the trials in other countries. As on 20.03.2013, as per the information available in www.clinicaltrials.gov of National Institute of Health, United States of America (USA), a total number of 1,42,239 clinical trials of different countries worldwide were registered. Out of these, 67,881 are from USA

38,473 from Europe, 10,702 from Canada, 2,645 from Japan, etc. Only, 2,178 clinical trials were registered from India.

Banning clinical trials, whether local or global, will not be in the interest of drug discovery and research in the country. However, there is a need to effectively monitor these trials so as to avoid irregularities therein. The Government has been continuously making efforts at strengthening the regulatory provisions and the monitoring mechanism of clinical trials in the country and to avoid irregularities therein. The provisions in the Drugs and Cosmetics Rules, 1945 relating to clinical trials have recently been amended as follows:

- (i) Amendment *vide* Gazette Notification G.S.R. 53 (E) dated 30.01.2013 specifying procedures to analyse the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.
- (ii) Amendment *vide* Gazette Notification G.S.R. 63(E) dated 01.02.2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.
- (iii) The registration of the Ethics Committees has been made mandatory in the Drugs and Cosmetics Rules *vide* Gazette Notification G.S.R No. 72(E) dated 08.02.13 specifying requirements and guidelines for registration of Ethics Committee.

Special allowances from below performing States

3785. SHRI N. K. SINGH:

DR. JANARDHAN WAGHMARE:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether Government proposes to make special allowances to supplement the expenditure of States which are below the national average on major public health indicators;
- (b) if so, the details thereof; and
- (c) if not, the reasons therefor?